REMARKS

Claims 1-22, 24, 25-27, 29 and 30 are pending before entry of this amendment.

Please note that the Office Action Summary sheet as mailed February 04, 2003 inaccurately fails to indicate the pending status of claim 24.

Please cancel claims 3, 5, 15, 16, 26 and 27 without prejudice or disclaimer.

Please amend claims 1, 2, 4, 20, 21, 22, 25 and 30 as shown above.

Please add new claim 31.

Applicants thank the Examiner for her assertion that Claim 25 would be allowable if rewritten in independent form incorporating all the limitations of the base and intervening claims. This has been done.

The claims have been amended to emphasize drug dilution from a first higher concentration to a second lower concentration *within* the diffusion space of the present invention *before* the diluted drug diffuses out through the claimed diffuser element to exit the device, which substantially distinguishes the present invention from that disclosed by Valli.

Amendments to Claims

Claim 1 has been amended to recite a drug delivery and dilution device wherein a drug at a first concentration is introduced into the elongate body inlet, moves through the elongate body passageway, out the elongate body outlet, and into the diffusion space, and further wherein water from the environment outside the device passes into the diffusion space through the diffuser element, wherein the water mixes with the drug, thereby diluting the drug to a second concentration within the diffusion space, and wherein said diluted drug then diffuses out through the diffuser element to exit the device. Support for this amendment may be found at, for example, paragraphs 13 and 48 of the specification.

Claim 2 has been amended to clarify the claimed limitation.

Claim 4 has been amended to incorporate the limitation of a diffuser element provided as a cap, as previously claimed in now canceled claim 5.

Claim 20 has been amended to remove a surplus word so as to clarify the claim.

Claim 21 has been amended to recite a drug reservoir containing Baclofen. Support for the amendment can be found in the specification at paragraph140.

Claim 22 has been amended to recite drug delivery in microliter or submicroliter quantities per day. Support for the amendment can be found in the specification at para.18.

Claim 25 has been amended according to the Examiner's suggestion to be in independent form and to include all the limitations of amended claim 1.

Claim 30 has been amended to clarify the exponent values of the claimed Diffusion Coefficient range.

Cancelled Claims

Claims 3, 5, 15, 16, 26 and 27 are cancelled without prejudice or disclaimer.

New Claim

New claim 31 recites the device of claim 1 wherein the diffuser element is substantially impermeable to drug and selectively permeable to water. Support for this limitation can be found in the specification at paragraph 9.

Rejections Under 35 U.S.C. §102(b)

Claims 1-22, 26, 27 and 29 are rejected as anticipated by Valli, 4,437,856.

The standard for an anticipation rejection is as follows:

> "...for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present." MPEP 706.02.

Valli does not teach every aspect of the currently claimed invention.

Claim 1 of the present application, as amended, recites a drug delivery and dilution device wherein a drug at a first concentration is introduced into the elongate body inlet, moves through the elongate body passageway, out the elongate body outlet, and into the diffusion space, and further wherein *fluid from the environment outside the device passes into the diffusion space through the diffuser element, wherein the fluid mixes with the drug, thereby diluting the drug to a*

second concentration within the diffusion space, and wherein said diluted drug then diffuses out through the diffuser element to exit the device. (Emphasis added)

Thus, in the presently claimed invention, dilution of the drug is achieved *internally* to the device (within the diffusion space), and *diluted drug* then diffuses out of the device to a delivery site to the patient.

This internal dilution is an important feature of the claimed invention because by diluting the drug before it exits the device, the invention reduces side effects such as toxicity and irritation to the surrounding tissue and also prevents precipitation of the drug in the outflow area (see paragraphs 23 and 24).

In the Valli device, no drug is delivered, no internal dilution occurs, and no diluted drug (or substance) is released from the device to the patient. Saline is simply pumped out of the device into the body cavity, the saline then mixes with the body fluids and is then sucked back into the device, essentially cleaning and dyalizing the fluid in the body cavity. *No dilution of any drug occurs within the device, and no diluted drug diffuses out of the device.*

In view of the above reasoning and amendments, Applicants assert that claim 1 is not anticipated by Valli. Claims 2, 4, 6-14, 17-22, 29 and 31 which depend from claim 1, are therefore also not anticipated by Valli. Applicants respectfully request that the rejection under 35 U.S.C. §102(b) be withdrawn.

Rejections Under 35 U.S.C. §103

Claim 30 is rejected as being unpatentable over Valli 4,437,856, and claim 29 is rejected as being unpatentable over Valli, in view of Burns et al. 5,221,260.

Applicants rebut these rejections because they do not meet the standards required to make a prima-face case of obviousness. The legal standards for establishing a prima face case of obviousness is well-established and clearly set out in the MPEP at 706.02(j).

> "To establish a prima face case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation ...to modify or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not [be] based on applicant's disclosure. In re Vaeck, 947 F.2d 488; 20 USPQ2d 1438 (Fed. Cir. 1991)."

Claim 30 is dependant on newly amended claim 1 which includes claim limitations that are not suggested or made obvious by the disclosure of Valli. The invention as claimed functions to dilute a drug internally *within* the claimed device, the *diluted drug* then exits the device.

The Valli device pumps saline out of the device, into the body fluid. The saline then mixes with the body fluids and is then sucked back into the device, dyalizing the body-cavity fluid. Valli does not describe the dilution of a drug, and certainly does not teach dilution of any substance within the device, which diluted substance/drug is then delivered from the device to the patient. Nothing in the Valli disclosure suggests or makes obvious the claimed invention.

Applicants thus request that the rejection under 35 USC §103(a) be withdrawn.

Claim 29, which is rejected over Valli, in view of Burns et al. Burns et al teaches a polymer balloon catheter. Since this claim is also dependant on newly amended claim 1, the same arguments as above may be employed to traverse the rejection. Applicants thus respectfully request that the rejection under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Attorney at (408) 864-7435.

The appropriate fee is attached or authorized. If the Commissioner determines that an additional fee is necessary, the Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. **50-1953.** **A duplicate copy of this communication is enclosed.**

Respectfully submitted,
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Dated: 4 April 2003.

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